



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/446,323

03/20/2000

STEFAN SANNER

258.00040101

2155

22204

7590

05/18/2006

NIXON PEABODY, LLP

401 9TH STREET, NW

SUITE 900

WASHINGTON, DC 20004-2128

EXAMINER

CROSS, LATOYA I

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/446,323	Applicant(s) SANNER, STEFAN	
	Examiner LaToya I. Cross	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-18 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on September 13, 2005. Claims 13-18 and 23 are pending. The claims were previously found to be allowable over the prior art. However, after further consideration, the claims are now believed to be obvious over the cited prior art, as outlined below. This action has been designated as non-final, so as to provide Applicants an opportunity to respond accordingly.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 13-18 and 23 are rejected under 35 U.S.C. 103(a) as being obvious over US Patent 4,534,939 to Smith et al.

Smith et al teaches a device for self-contained coagulation detection. The device comprises a housing (24) in which a cartridge (52), testing means (74) and sample taking means (102) are positioned. The cartridge contains activator reagent. The activator reagent is preferably retained substantially within an enclosure defined by an inverted cup-shaped structure (54). The activator agent (52) is thereby confined between the inverted cup-shaped structure (54) and the partition (38). The cup shaped structure (54) is glued or otherwise fastened to the interior surface of the lower portion (48) by a spot of adhesive (56). The testing means is a chamber defined by (60) and partition (38). The sample taking means comprises a syringe which, by definition, inherently includes a chamber. Additionally, the cartridge and testing

Art Unit: 1743

means are brought into contact with the sample mixture for analyzing this mixture. See figures 11-16.

Smith et al differ in that there is no disclosure of the sample-taking means being comprised of two half-tubes that are connected to each other. While the Examiner recognizes this difference between the reference and Applicants' claim, the Examiner takes the position that making the sample-taking means a two-part component is insufficient to make the claims patentable. MPEP 2144.04(V)(C), citing In re Dulberg states that it would be obvious to make a structure separable if it were considered desirable for any reason to obtain access into the structure. In the instant case, one of ordinary skill in the art would have recognized that gaining access to the inside of the sample-taking means would be advantageous if only for the reason of removing sample from or putting sample into the sample-taking means manually.

2. Claims 13-18 and 23 are rejected under 35 U.S.C. 103(a) as being obvious over US Patent 6,048,735 to Hessel et al in view of US patent 5,096,699 to Lauks et al.

Hessel et al teaches a multi-sectioned fluid delivery device for immunoassay detection. The device comprises a housing (6) in which a plurality of cartridges (8), testing means (1) and sample taking means (e.g. inside cap 16) are positioned. The biological sample is placed in the cap and the cap is fitted onto the distal end of the syringe portion (9). The testing means is a sensor laminate (1) and permits binding of any target molecule in the sample to the reactive substrate layer (3) of the sensor laminate. The turning handle (14) is then rotated so that the plunger (15), sensor laminate (1) and piercing element (7) move toward the distal end of the syringe (9) extending into the cap (16) so that the piercing element (7) sequentially pierces each

Art Unit: 1743

divider (18) of each compartment (8) thereby displacing the compartments and releasing the fluids in an ordered sequence to detect any bound target molecules on the sensor laminate (1). (See col. 9, line 20 – col. 10, line 54; figures 4-6).

Hessel et al differ in that there is no disclosure of the sample-taking means being comprised of two half-tubes that are connected to each other. While the Examiner recognizes this difference between the reference and Applicants' claim, the Examiner takes the position that making the sample-taking means a two-part component is insufficient to make the claims patentable. MPEP 2144.04(V)(C), citing In re Dulberg states that it would be obvious to make a structure separable if it were considered desirable for any reason to obtain access into the structure. In the instant case, one of ordinary skill in the art would have recognized that gaining access to the inside of the sample-taking means would be advantageous if only for the reason of removing sample from or putting sample into the sample-taking means manually.

Response to Arguments

4. Applicant's arguments are moot in view of the new grounds of rejection set forth above.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya C. Younger whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lcy


MONIQUE T. COLE
PRIMARY EXAMINER